K123267

510(k) SUMMARY

NOV 2 2012

Prepared by **Sandi Hartka**
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Date prepared : September 11, 2012

Prepared for : **Owner/Operator**

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A. DEVICE NAME

Proprietary Name
SURFLASH® Plus Safety I.V. Catheter

Classification Name
Intravascular Catheter

Intravascular Catheter (880.5200)
Product Code: FOZ
Panel: General Hospital
Classification: Class II

Common Name
Intravascular catheter with needle protection device

B. INTENDED USE

The SURFLASH® Plus Safety I.V. Catheter is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluid intravenously, or monitor blood pressure by attaching a monitoring line. The needle shaft cover and tip shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy. The 18 to 22 gauge catheters are suitable for use with power injectors rated for a maximum of 325 psi.

C. DEVICE DESCRIPTION (SUMMARY OF TECHNOLOGICAL CHARACTERISTICS)

Principle of Operation/Technology
The SURFLASH® Plus Safety I.V. Catheter is manually operated and contains a passive safety feature that automatically activates as the needle is withdrawn from the catheter.

Design / Construction

The SURFLASH® Plus Safety I.V. Catheter are devices consisting of catheter assembly (catheter, caulking pin and catheter hub containing valve, seal component and plug), needle assembly (needle, needle housing, transparent flash chamber with filter and needle protector) and a passive needle-shielding mechanism (shutter and needle shaft cover consisting of inner cylinder, outer cylinder, junction cylinder).

The SURFLASH® Plus Safety I.V. Catheter has a valve and a seal component inside the catheter hub to minimize the possibility of blood leakage at catheter hub after needle removal. The catheter hub is also provided with a plug inside which penetrates the valve to create a fluid path when a connector is inserted in the catheter hub. The fluid path is permanently opened once a secure luer connection is made.

The devices are an over-the needle, peripheral catheter made of a slender, flexible, radio-opaque plastic with a hub that is inserted into the patient's vascular system for short term (<30 days) use to withdraw blood samples, administer fluids intravenously, or monitor blood pressure by attaching a monitoring line.

Whole length cannula including the sharp end of the inner needle is covered by the needle shielding mechanism as the needle is withdrawn from catheter's hub to aid in the prevention of needle stick injuries.

The grooved cannula which allows the clinician to visualize flashback detection through the groove indicating that there is confirmation of vessel entry is the same as the TERUMO® Surshield®-PUR Safety I.V. Catheter (K100282) and TERUMO® SURFLASH® I.V. Catheter (K991406).

Material

The stainless steel cannula is placed in the catheter to maintain rigidity and is withdrawn after the catheter is placed in the vascular system.

The catheter that is advanced into the vessel is made of polyurethane which is the same as the TERUMO® Surshield®-PUR Safety I.V. Catheter (K100282) and TERUMO® SURFLASH® I.V. Catheter (K991406).

Specifications

The SURFLASH® Plus Safety I.V. Catheter are available in 6 sizes with combination of 18, 20, 22 and 24 gauge catheters diameters and 19, 25 and 32 mm catheters length.

D. NON-CLINICAL TESTS

Performance testing was conducted to ensure the safety and effectiveness of the SURFLASH® Plus Safety I.V. Catheter throughout the shelf life, to verify conformity to the applicable part of ISO standards and demonstrate substantial equivalence to the predicate devices as mentioned in the table on next pages.
No new issues of safety and effectiveness were raised with the testing performed.
Performance testing demonstrates that the SURFLASH® Plus Safety I.V. Catheter conforms to the recognized consensus ISO standards, is substantially equivalent to the predicate devices and acceptable for clinical use throughout the shelf life.

A simulated use study was conducted in accordance with FDA's Guidance For Industry and Staff, Medical Devices with Sharps Injury Prevention Features issued on August 9. 2005. The objectives of this study were designed to confirm that study participants are able to read and follow the Instructions for Use to safely and effectively operate the safety feature of the device. The objectives were:

1. Verify that proper activation of the sharps injury prevention feature of the device can be accomplished in simulated clinical environments by healthcare workers who use these types of safety I.V. catheters.
2. Determine if the Instructions for Use are adequate for proper activation of the sharps injury prevention feature.

All safety features activated effectively and there were no de-activations after discarding. All participants were able to read and activate the catheter safety feature without further explanation or training. No adverse events occurred.

Conclusion: The safety feature of the device operates safely and effectively as intended. Users with various levels of experience can read the IFU and operate the device safely and effectively.

Terumo Corporation
TERUMO® SURFLASH® Plus Safety I.V. Catheter
Response to Comments dated September 20, 2012

Attachment 2

Performance test	Testing			
	Compliance to ISO			Testing by internal standard
	ISO 10555-1	ISO 10555-5	ISO 23908	
Force to needle breaking shutter (Puncture resistance of needle shield)	Not required	Not required	X	Required by SO
Tensile strength of needle shaft and needle housing (Break strength of safety mechanism)	Not required	Not required	X	Required by ISO
Force to release shutter and reactive force when the shutter opens to cover the cannula tip (Reaction force generated by the activation mechanism)	Not required	Not required	Not required	X
Force to detach needle shaft cover from catheter hub (Force to activate safety feature)	Not required	Not required	X	Required by ISO
Simulated maximum pressure	Not required	Not required	Not required	X
Burst pressure (whole device)	X	Not required	Not required	Required by ISO
Collapse (under negative pressure)	X	Not required	Not required	Required by ISO
Catheter to catheter hub tensile strength (Force at break of catheter / hub)	X	Not required	Not required	Required by ISO
Strength of union between transparent flash chamber (needle connecting part) and needle	Not required	X	Not required	Required by ISO
Needle attachment to catheter (Initial sliding friction)	Not required	Not required	Not required	X
Detection of flashback at catheter tip	Not required	Not required	Not required	X
Detection of flashback at transparent flash chamber (needle connecting part)	Not required	X	Not required	Required by ISO
Flow rate	Not required	X	Not required	Required by ISO
Vent fitting	Not required	X	Not required	Required by ISO
Protector attachment (Drop test)	Not required	Not required	Not required	X
Conical fittings of catheter hub	X	Not required	Not required	Required by ISO
Pressure monitoring	Not required	Not required	Not required	X
Blood leakage at catheter hub	Not required	Not required	Not required	X
Measurement of valve penetration resistance to catheter hub	Not required	Not required	Not required	X
Simulated use study	Not required	Not required	X	Required by ISO
Corrosion resistance	X	Not required	Not required	Required by ISO
Catheter body tensile strength (Force at break)	X	Not required	Not required	Required by ISO
Stiffness	Not required	Not required	Not required	X
Elongation	Not required	Not required	Not required	X
Flexural fatigue tolerance	Not required	Not required	Not required	X
Radio-detectatbility	Not required	X	Not required	Required by ISO
Surface	X	Not required	Not required	Required by ISO
Catheter unit	Not required	X	Not required	Required by ISO
Needle point	Not required	X	Not required	Required by ISO

X: Confirmed the conformance to the standard.

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The SURFLASH® Plus Safety I.V Catheter is classified as

-Catheter and lubricant: Externally Communicating Device, Circulating Blood, Prolonged Exposure (24hrs – 30 days).
-All other materials contacting with patient's body: Externally Communicating Devices, Blood path indirect, Prolonged Exposure (24 hrs to 30 days)

As mentioned below table, the device's materials contacting with patient's body were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO – 10993, "Biological Evaluation of Medical Devices part 1: Evaluation and Testing." Screening tests were performed on accelerated aged whole devices to show that the biocompatibility is maintained throughout the shelf life of the product. Results of the testing demonstrate that the materials contacting with patient's body are biocompatible throughout the shelf life of the product.

Test
Cytotoxicity
Sensitization
Intracutaneous reactivity
Systemic toxicity (acute)
Pyrogen
Genotoxicity
Implantation / Subchronic toxicity
Hemolysis
Physicochemical
Characterization

E. ADDITIONAL SAFETY INFORMATION

The sterility of the device is assured using a sterilization method validated in accordance with Method C: Half-cycle method in Annex B of ANSI/AAMI/ISO 11135: Sterilization of health care products – ethylene oxide. The product is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

F. SUBSTANTIAL EQUIVALENCE

The SURFLASH® Plus Safety I.V. Catheter manufactured by Terumo Corporation is substantially equivalent to:

1. K100282 TERUMO® Surshield®-PUR Safety I.V. Catheter (Terumo Corporation)
2. K991406 TERUMO® SURFLASH® I.V. Catheter (Terumo Corporation)
3. K110443 BD Insyte Autoguard BC shielded I.V. Catheter (Becton Dickinson)
4. K971339 BD Insyte™ Autoguard™ shielded I.V. Catheter (Becton Dickinson)
4. K923702 Saf-T-Intima Closed IV Catheter System (Becton Dickinson)

Comparison of the intended use/indication for use statements and technological characteristics are summarized in the following pages.

The minor differences of intended use and the technological differences do not impact the safety and effectiveness of the device in clinical settings.

G. CONCLUSION

The SURFLASH® Plus Safety I.V. Catheter is substantially equivalent to the predicate devices in intended use and technological characteristics.

Comparison of Intended Use/Indications for Use statements

SURFLASH® Plus Safety I.V. Catheter intended use/indications for use statements are different from those of the predicate devices as mentioned below.

Section	SURFLASH®Plus Safety I.V. Catheter (subject of this 510k)	TERUMO® Surshield® –PUR Safety I.V. Catheter K100282	TERUMO®SURFLASH® I.V. Catheter K991406	BD Insyte Autoguard BC shielded I.V. Catheter K110443	BD Insyte Autoguard shielded I.V.Catheter K971339	BD Saf-T-Intima Closed I.V. Catheter System K923702
I			Is a device consisting of a slender, flexible, radiopaque, plastic catheter with hub. The stainless steel cannula, placed in the catheter to maintain rigidity, is withdrawn after the catheter is placed in the vascular system.			The device consists of a slender, flexible, radiopaque, plastic catheter with a hub… (see below section) The steel needle (stylet) placed in the catheter to maintain rigidity is withdrawn after

Section	SURFLASH®Plus Safety I.V. Catheter (subject of this 510k)	TERUMO® Surshield® –PUR Safety I.V. Catheter K100282	TERUMO®SURFLASH® I.V. Catheter K991406	BD Insyte Autoguard BC shielded I.V. Catheter K110443	BD Insyte Autoguard shielded I.V.Catheter K971339	BD Saf-T-Intima Closed I.V. Catheter System K923702
						the catheter is placed in the vascular system
II	Inserted into patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluid intravenously, or monitor blood pressure by attaching a monitoring device	Inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluid intravenously, or monitor blood pressure by attaching a monitoring line.	The plastic catheter is inserted into the patient's vascular system for short term use to withdraw samples, administer fluid intravenously or through which to place monitoring equipment such as pressure monitors.	The BD Insyte Autoguard BC catheter is inserted into a patient's vascular system to sample blood, monitor blood pressure, or administer fluids.	As indicated in 21CFR 870.1200, to sample blood, to monitor blood pressure, or to introduce substances into the heart and vessels. *Note: FDA classified this device in K971339 as substantially equivalent pursuant to 21CFR 880.5200; this is*	…that is inserted into the patient's vascular system for short-term use to sample blood, monitor blood pressure, or administer fluids intravenously.

Section	SURFLASH®Plus Safety I.V. Catheter (subject of this 510k)	TERUMO® Surshield® –PUR Safety I.V. Catheter K100282	TERUMO®SURFLASH® I.V. Catheter K991406	BD Insyte Autoguard BC shielded I.V. Catheter K110443	BD Insyte Autoguard shielded I.V.Catheter K971339	BD Saf-T-Intima Closed I.V. Catheter System K923702
					the classification that applies to the proposed device and the predicate devices in this subject 510k.	
III	The needle shaft cover & tip shield feature aids in the prevention of needle stick injuries	The needle shield feature aids in the prevention of needle stick injuries.				
IV	These catheters may be used for any patient population with consideration give	These catheters may be used for any patient population with consideration			These catheters may be used for any patient population with consideration give	

Section	SURFLASH®Plus Safety I.V. Catheter (subject of this 510k)	TERUMO® Surshield® –PUR Safety I.V. Catheter K100282	TERUMO®SURFLASH® I.V. Catheter K991406	BD Insyte Autoguard BC shielded I.V. Catheter K110443	BD Insyte Autoguard shielded I.V.Catheter K971339	BD Saf-T-Intima Closed I.V. Catheter System K923702
	to adequacy of vascular anatomy & appropriateness for the solution being infused & duration of therapy	given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy			to patient size, appropriateness for the solution being infused, and duration of therapy.	
V	The 18- 22 G catheters are suitable for use with power injectors rated for a maximum of 325 psi.				The catheters maybe used with power injectors for which the maximum rated pressure is 300 psi.	

Discussion of Sections of the Intended Use/Indications for Use

I. Device Descriptive section (Full physical description of the device):

A full physical description of the device is not necessary for a discussion in the Intended Use/Indications for Use section. Omission of a physical description in the Intended Use/Indications for use of the proposed device subject of this 510k is not relevant to a comparison of the device's intended use/indication for use. Comparison of the physical description is presented in the comparison of technological characteristics of this 510k. The omission of a physical description in the Intended Use/Indication for use has no impact on the safety and effectiveness. The physical attributes of the proposed device have been tested and compared to the appropriate predicate that has the same/similar physical attribute.

II. Basic Device description and use as prescribed in 21CFR 880.5200

The proposed device and the predicate devices are classified under 21CFR880.5200 which states:

"An intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings and that is inserted into the patient's vascular system for short term use (less than 30 days) to sample blood, monitor blood pressure or administer fluids intravenously. The device may be constructed of metal, rubber, plastic, or a combination of these materials."

The proposed device and the predicate devices use a similar statement (underlined portion) regarding the actual use of the device.

Note: BD Insyte Autoguard states in the 510k that the device is classified under 21CFR 870.1200, however, FDA has classified this 510k (K971339) under 21CFR880.5200 which is identical to the proposed device subject of this 510k and the predicate devices.

III. Description of Sharps Injury Protection

Terumo has included the description of the sharps injury protection feature in the Intended Use/Indications for Use statement for the proposed device and for one predicate device (TERUMO® Surshield® –PUR Safety I.V. Catheter (K100282). Although three of the other predicate devices (K110443, K971339 & K923702) contain a sharps injury protection feature, the manufacturers have not included this description in their Intended Use/Indication for Use statement of their cleared 510k (this feature is discussed in the Technological Characteristics section). Even though the descriptive statement does not appear in the Intended Use/Indication for Use for those predicates, the feature is cleared under the respective 510ks.

Note: The predicate cleared under K991406 does not include a sharps injury protection feature as discussed in the Technological Characteristics section and, therefore, does not have this feature described herein.

IV. Discussion of usage in populations

The proposed device and two of the predicate devices (K100282 and K971339) clarify that these devices may be used in any population based on medical judgment. There is no restriction placed on the use of devices in any specific population and no specific indication of use in a specific population, but rather the statement indicates these devices can be used wherever medical judgment deems appropriate. These devices are general medical use devices and can be used in any population deemed acceptable by a medical professional. These devices are "Rx only."

These clarifying statements have no impact on the general use of the products and do not affect the safety or effectiveness nor the determination of substantial equivalence.

V. Use with Power Injectors

The proposed device and one of the predicate devices (K971339) include an indication for use with Power Injectors. The other three predicate devices do not include this indication. Appropriate testing has been included in this 510k to address the new issues of safety and effectiveness raised by this indication. The test results demonstrate the substantial equivalence of this indication with the product covered under K971339. This indication in

the 510(k) subject device has no impact on the other indications for use for which substantial equivalence is being claimed. This indication can effectively be reviewed separately regarding substantial equivalence.

Comparison of the technological characteristics to predicate devices

Technological characteristics of SURFLASH® Plus Safety I.V. Catheter are similar to the predicate devices in terms of principle of operation, design/construction, material and specifications as mentioned in below table.

Trade Name	**SURFLASH® Plus Safety I.V. Catheter** **Subject of this 510(k)**	**TERUMO® Surshield®-PUR Safety I.V. Catheter** **K100282**	**TERUMO® SURFLASH® I.V. Catheter** **K991406**	**BD Insyte Autoguard BC shielded I.V. Catheter** **K110443**	**BD Insyte Autoguard shielded I.V. Catheter** **K971339**	**Saf-T-Intima Closed IV Catheter System** **K923702**
Manufacturer	Terumo Corporation	Terumo Corporation	Terumo Corporation	Becton Dickinson	Becton Dickinson	Becton Dickinson
Operation principle	Conduit as fluid pathway Operated manually.	Conduit as fluid pathway Operated manually.	Conduit as fluid pathway Operated manually.	Conduit as fluid pathway Operated manually.	Conduit as fluid pathway Operated manually.	Conduit as fluid pathway Operated manually
Design /Construction	a. Catheter assembly b. Needle assembly c. Needle shield assembly d. Filter e. Needle protector f. Valve g. Seal component h. Plug	a. Catheter assembly b. Needle assembly c. Needle shield assembly d. Filter cap with filter e. Protector	a. Catheter assembly b. Needle assembly c. Filter cap with filter d. Protector	a. Catheter assembly b. Needle assembly c. Needle shield assembly d. Filter e. Needle protector f. Valve (called Septum) g, plug*	a. Catheter assembly b. Needle assembly c. Needle shield assembly d. Filter e. Needle protector	a. Catheter assembly with tube and I or Y adaptor b. Needle assembly c. Needle shield d. Filter cap with air filter e. Needle cover f. IV access port g. Wings available
Needle Shape/Material	Notched cannula Stainless steel	Notched cannula Stainless steel	Notched cannula. Stainless steel	Holed cannula. Stainless steel	Holed cannula. Stainless steel	Notched cannula.
Flashback	Visible through	Visible through	Visible through	Visible through hole	Visible through hole	Visible through

Trade Name	**SURFLASH® Plus Safety I.V. Catheter** **Subject of this 510(k)**	**TERUMO® Surshield®-PUR Safety I.V. Catheter** **K100282**	**TERUMO® SURFLASH® I.V. Catheter** **K991406**	**BD Insyte Autoguard BC shielded I.V. Catheter** **K110443**	**BD Insyte Autoguard shielded I.V. Catheter** **K971339**	**Saf-T-Intima Closed IV Catheter System** **K923702**
	ditch on the cannula surface.	ditch on the cannula surface.	ditch on the cannula surface.	on the cannula surface.	on the cannula surface.	needle lumen to tube.
Catheter material	Polyurethane Biocompatibility of material confirmed.	Polyurethane Biocompatibility of material confirmed.	Polyurethane Biocompatibility of material confirmed.	Polyurethane	Polyurethane	Polyurethane
Radiopaque medium	Yes (Barium sulfate)	Yes (Barium sulfate)	Yes (Barium sulfate)	Yes (material not identified)	Yes (material not identified)	Yes (material not identified)
Safety mechanism	Passive needle shielding	Passive needle shielding	None	Passively needle shielding	Passively needle shielding	Passive needle shielding
Valve	YES to reduce the blood leakage at catheter hub in view of blood exposure risk	No	No	YES to reduce the blood leakage at catheter hub in view of blood exposure risk	No	No
Color code of catheter hub	In accordance with ISO 10555-5	In accordance with ISO 10555-5	In accordance with ISO 10555-5	In accordance with ISO 10555-5	In accordance with ISO 10555-5	In accordance with ISO 10555-5
Package	Sterility barrier: Blister package Unit box Cardboard	Sterility barrier: Casing Unit box Cardboard	Sterility barrier: Casing Unit box Cardboard	Sterility barrier: Blister package	Sterility barrier: Blister package	Sterility barrier: Blister Package
Sterilization method	Ethylene oxide	Ethylene oxide	Ethylene oxide	Ethylene oxide	Ethylene oxide	Ethylene oxide

Conclusion

SURFLASH® Plus Safety I.V. Catheter and the predicate devices have the same Technological Characteristics except that

- The predicate cleared under K991406 does not include a sharps injury protection feature as mentioned in the above table.
- The predicates cleared under K100282, K991406, K971339 and K923702 do not include a valve as mentioned in the above table.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Kofu Factory of Terumo Corporation
C/O Terumo Medical Corporation
Ms. Sandi Hartka
Regulatory Affairs Manager
950 Elkton Boulevard
Elkton, Maryland 21921

November 2, 2012

Re: K123267
Trade/Device Name: SURFLASH® Plus Safety I.V. Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: October 18, 2012
Received: October 19, 2012

Dear Ms. Hartka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Anthony D. Watson
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402
Date: 2012.11.02 13:08:22 -04'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K123267

Device Name: SURFLASH® Plus Safety I.V. Catheter

Indications for Use:

The SURFLASH® Plus Safety I.V. Catheter is inserted into the patient's vascular system for short term use (<30 days) to withdraw blood samples, administer fluid intravenously, or monitor blood pressure by attaching a monitoring line. The needle shaft cover and tip shield feature aids in the prevention of needle stick injuries. These catheters may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness for the solution being infused and duration of therapy. The 18 to 22 gauge catheters are suitable for use with power injectors rated for a maximum of 325 psi.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/1/2012

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123267